

### **Listing of Claims**

1. (Currently Amended) A removable aerosolizing element for use in an aerosol delivery device for aerosolizing an agent, comprising:
  - a body having an exterior surface and a chamber defined therein;
  - an inlet defined in the body for connection to a source of agent, the inlet being in fluidic communication with the chamber;
  - agent releasing orifices defined in the body and in communication with the chamber;
  - a movable element having an inner surface that defines a portion of the chamber, the movable element being capable of moving in response to an external force applied to the exterior surface, wherein the external force causes the movable element to move toward the agent releasing orifices to increase pressure in the chamber and cause to expel agent in the chamber to be expelled through the orifices; and
  - projections disposed in the chamber and maintaining a minimum spacing between the moveable element and the orifices, the projections being configured to contact the inner surface of the moveable element and an opposing inner surface of the chamber defining said orifices to maintain the minimum spacing when the external force is applied to the exterior surface.
2. (Original) The aerosolizing element of claim 1, wherein the movable portion is deformable, and the movable portion deforms under the external force to increase pressure in the chamber, thereby expelling agent from the chamber through the orifices.
3. (Original) The aerosolizing element of claim 1, wherein the movable element comprises a flexible diaphragm.
4. (Original) The aerosolizing element of claim 1, wherein the chamber includes an internal passageway portion in communication with the inlet and a main chamber portion generally opposite the orifices.

5. (Original) The aerosolizing element of claim 1, wherein the chamber is filled with a predetermined quantity of agent and the inlet is sealed.
6. (Previously Presented) The aerosolizing element of claim 1, further comprising a cover positioned over the inlet to reduce entry of undesired material into the chamber.
7. (Original) The aerosolizing element of claim 1, wherein the body comprises an orifice plate partially bounding the chamber generally opposite the movable element, the orifice plate defining the orifices.
8. (Original) The aerosolizing agent of claim 7, wherein the orifice plate comprises a metal foil.
9. (Original) The aerosolizing element of claim 1, wherein the chamber can be filled with agent via gravity feed from the inlet.
10. (Original) The aerosolizing element of claim 1, wherein the chamber can be filled with agent via capillary action.
11. (Previously Presented) The aerosolizing element of claim 1, wherein the projections are dimensioned to contact the inner surface of the moveable element and the opposing inner surface of the chamber when the external force is not applied to the moveable element.
12. (Original) The aerosolizing element of claim 1, wherein the external force applied to the movable member comprises vibratory oscillations causing the movable member to reciprocate and alternately increase pressure in the chamber to expel agent and decrease pressure to draw additional agent into the chamber.

13. (Original) The aerosolizing element of claim 1, wherein the element is pre-filled with at least a first component and a second component of an agent to be aerosolized that are mixed within the element prior to aerosolization.

14. (Original) The aerosolizing element of claim 13, wherein body comprises a first reservoir pre-filled with the first component of the agent, a second reservoir pre-filled with the second component of the agent, and a separation element disposed between the first and second reservoirs and separating the first component from the second component, the separation element being movable into the first reservoir to allow mixing of the first and second components.

15. (Original) The aerosolizing element of claim 1, wherein the body includes a needle portion shaped to receive a vial of agent and wherein an end of the needle defines the inlet.

16. (Original) The aerosolizing element of claim 1, wherein the element is disposable after use.

17. (Original) The aerosolizing element of claim 1, wherein one side of the body is adapted for direct attachment to a patient interface for conveying aerosolized agent from the orifices towards a patient.

18. (Original) The aerosolizing element of claim 1, wherein the chamber includes an air vent separate from the inlet.

19. (Original) The aerosolizing element of claim 1, wherein:  
the aerosol delivery device comprises an actuator that applies the external force to the movable element to cause the agent to be expelled through the orifices; and  
the body is configured to prevent the agent from contacting the actuator.

20. (Original) The aerosolizing element of claim 1, further comprising at least one airflow passageway extending through the body such that air flowing through the passageway can carry the expelled agent away from the element.

21. (Original) The aerosolizing element of claim 20, wherein the airflow passageway comprises an inlet defined in one side of the body and an outlet defined in an opposing side of the body, the outlet being offset from the inlet.

22. (Original) The aerosolizing element of claim 1, wherein the body comprises first and second reflective surfaces positioned on opposite sides of the orifices such that a light beam passing through the element is reflected by the first reflective surface to extend in front of the orifices and onto the second reflective surface, which reflects the light beam back through the element.

23. (Original) The aerosolizing element of claim 22, wherein the body comprises a transparent material that transmits the light beam.

24. (Currently Amended) The aerosolizing element of claim 3, wherein the ~~flexible diaphragm comprises a plurality of projections that maintain a minimum chamber thickness~~ are on the flexible diaphragm.

25. (Original) The aerosolizing element of claim 3, wherein the body comprises an opening adjacent the flexible diaphragm, the opening being adapted to receive an actuator for coupling to the flexible diaphragm and applying the external force.

26. (Currently Amended) An aerosolizing device, comprising:  
a housing sized and shaped to be held in a hand of a user;  
a disposable aerosolizing element disposed in the housing and capable of expelling aerosolized agent, the aerosolizing element comprising a chamber, agent releasing orifices, a movable element opposite the agent releasing orifices, and projections disposed in the chamber and configured to maintain a minimum spacing between the movable element and the orifices;  
an oscillator disposed in the housing and positioned to exert vibratory oscillations on a ~~portion~~ the movable element of the disposable aerosolizing element to aerosolize agent in the element; and  
a patient interface coupled to the housing and shaped to deliver aerosolized agent expelled from the disposable aerosolizing element to a patient,  
wherein the disposable aerosolizing element is removable from the housing for installation and disposal.

27. (Original) The device of claim 26, further comprising a compressed air source configured to supply compressed air to the device to assist in delivery of aerosolized agent through the patient interface.

28. (Original) The device of claim 27, wherein some of the air conveyed by the compressed air source is directed to cool the oscillator.

29. (Original) The device of claim 26, further comprising air inlet holes positioned to allow entry of atmospheric air into the device to assist in delivery of aerosolized agent through the patient interface.

30. (Original) The device of claim 26, wherein the disposable aerosolizing element has ~~an internal chamber at least partially defined by~~ a flexible portion at least partially defining the chamber, wherein the flexible portion ~~that~~ can be manually squeezed by a user to create a negative pressure within the chamber to assist in filling the chamber with agent.

31. (Original) The device of claim 26, wherein the disposable aerosolizing element has an inlet for receiving an agent to be aerosolized and prevents the agent from contacting the oscillator.

32. (Original) The device of claim 26, further comprising:  
a body-mountable pack that is worn or carried on the user's body; and  
a power source for the device comprising one or more batteries disposed in the pack.

33. (Original) The device of claim 32, further comprising an air pump disposed in the pack and an air conduit fluidly connecting the air pump to the housing, the air pump being operable to supply compressed air to the housing to assist in delivery of aerosolized agent through the patient interface.

34. (Original) The device of claim 32, wherein the pack is worn around the user's waist or on the user's shoulder.

35. (Original) The device of claim 26, wherein the patient interface comprises a disposable mask shaped to fit around the mouth and nose of the patient.

36. (Original) The device of claim 35, wherein the mask comprises a material that is porous to air.

37. (Original) The device of claim 26, wherein the patient interface comprises a one-way valve that is operable to permit flow from the disposable aerosolizing element to the patient through the patient interface, and to inhibit flow in the reverse direction through the patient interface.

38. (Original) The device of claim 37, wherein the one-way valve comprises a duckbill valve.

39. (Original) The device of claim 26, wherein the patient interface comprises one or more baffles that shield the disposable aerosolizing element from expired particles.

40. (Original) The device of claim 26, further comprising an aerosolization rate monitor that is operable to detect the rate at which agent is aerosolized by the aerosolizing element.

41. (Original) The device of claim 26, further comprising a counting device that is operable to record the number of doses that are administered by the device.

42. (Currently Amended) A handheld aerosolizing device, comprising:  
~~a disposable~~ an aerosolizing element capable of expelling aerosolized agent, the aerosolizing element comprising a front portion having an opening extending completely therethrough, a rear portion having an opening extending completely therethrough, a chamber defined between the front and rear portion, an orifice plate aligned with the opening in the front portion, and a flexible diaphragm aligned with the opening in the rear portion opposite the orifice plate;

~~a battery powered~~ an actuator coupled to the flexible diaphragm through the opening of the rear portion of the aerosolizing element positioned to exert vibratory oscillations on a portion of the flexible diaphragm of the disposable aerosolizing element to aerosolize agent in the element, wherein aerosolized agent is expelled through orifices in the orifice plate and the opening in the front portion of the aerosolizing element; and

~~a patient interface shaped to deliver aerosolized agent expelled from the disposable aerosolizing element to a patient,~~

wherein the aerosolizing element prevents the agent from contacting the actuator.

43. (Original) The device of claim 42, wherein a fluid passageway from a source of agent to the patient interface is substantially contained within the aerosolizing element and the element is separately removable from the device.

44. (Original) The device of claim 43, wherein the source of agent is contained within the aerosolizing element.

45. (Original) The device of claim 43, wherein the aerosolizing element is shaped for direct connection to the source of agent.

46. (Previously Presented) The device of claim 42, wherein the aerosolizing element is pre-filled with a volume of agent.

47. (Original) The device of claim 46, wherein the volume of agent is sufficient for delivery of multiple single doses.

48. (Original) The device of claim 47, further comprising a vial containing agent for direct coupling to the aerosolizing element.

49. (Original) The device of claim 42, wherein the patient interface comprises a mask intended for disposal after each use.

50. (Original) The device of claim 42, wherein the patient interface comprises a mask intended for disposal after each use that is porous and entraps expired aerosols from the patient.

51. (Original) The device of claim 42, wherein the patient interface is a nasal prong intended for disposal after each use.

52. (Original) The device of claim 42, further comprising an aerosolization rate monitor that allows monitoring of aerosolizing rates during use.

53. (Original) The device of claim 52, wherein the aerosolization rate monitor comprises a light source operable to project a light beam that extends through aerosol droplets being expelled by the aerosolizing element and a light detector operable to detect the obscuration of the light beam caused by the aerosol droplets.



54. (Original) The device of claim 53, wherein the aerosolization rate monitor comprises a controller and a visual indicator, wherein the controller receives the signal from the light detector and determines an aerosolization rate based on the signal, and the visual indicator provides a visual indication regarding the aerosolization rate.

55. (Original) The device of claim 53, wherein the aerosolizing element comprises first and second reflective surfaces, the first reflective surface being positioned to reflect the light beam from the light source to extend in a first direction through the aerosol droplets, the second reflective surface being positioned to reflect the light beam extending through the aerosol droplets to extend in a second direction toward the light detector.

56. (Currently Amended) The device of claim 42, wherein at least the aerosolizing element and the ~~oscillator~~ actuator are arranged together in a housing sized for holding in a hand of user.

57. (Currently Amended) The device of claim ~~42~~ 56, further comprising a component separate from the housing in which at least batteries are positioned, the component having a power connection to the housing providing an electrical connection from the batteries to the actuator, the component being ~~and~~ adapted to be worn or carried on a user's body.

58. (Currently Amended) A method of using an aerosolizing device, the method comprising administering an aerosolized agent from the aerosolizing device by applying vibratory oscillations to a disposable aerosolizing element in the aerosolizing device and disposing of the aerosolizing element after administering the agent, wherein the aerosolizing element comprises a chamber, agent releasing orifices, a movable element opposite the agent releasing orifices, and projections disposed in the chamber and configured to maintain a minimum spacing between the movable element and the orifices.

59. (Previously Presented) The aerosolizing element of claim 1, wherein the projections are formed on the moveable element.

60. (Previously Presented) The aerosolizing element of claim 1, wherein the projections have a height of about 0.1 mm equal to the minimum spacing of the chamber.

61. (Previously Presented) The aerosolizing element of claim 1, wherein the orifices are formed by laser drilling.

62. (Previously Presented) The aerosolizing element of claim 1, wherein the projections are configured to allow agent to flow through the chamber when the projections are in contact with the inner surface of the movable element and the opposing inner surface of the chamber.

63. (Previously Presented) The aerosolizing element of claim 1, in combination with the aerosol delivery device, the aerosol delivery device comprising an ultrasonic horn coupled to the moveable element and comprising an actuator and a motion transmitting member coupling the actuator to the moveable element for transferring vibratory motion of the actuator to the moveable element.